DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 29 2002

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harry W. Snyder, Jr.
8225 Colonial Woods Drive
Boerne, Texas 78015

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 01N-0565

Dear Mr. Snyder:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product. This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Conviction

On March 23, 2000, you were convicted on all five counts of an indictment consisting of: two counts of making false statements to an agency of the United States, a Federal felony offense under 18 U.S.C. 2 and 1001; two counts of mail fraud, a Federal felony offense under 18 U.S.C. 2 and 1341; and one count of conspiracy to commit offenses against the United States, a Federal felony under 18 U.S.C. 371. On August 31, 2000, the United States District Court for the Northern District of Alabama sentenced you for these offenses. The underlying facts supporting this felony conviction are as follows:

At the time of your criminal actions, you were vice president of clinical development at BioCryst Pharmaceutical, Inc. (BioCryst), a company formed for the purpose of developing, testing, and marketing pharmaceutical drugs. BioCryst was developing the drug BCX-34, a skin cream for the treatment of psoriasis and T-cell lymphoma, under an investigational new drug application (IND) before the FDA. You were responsible for overseeing studies to test the effectiveness of BCX-34 in the treatment of psoriasis and T-cell lymphoma.

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Upon finding discrepancies in the study results, Dr. Cook, the medical director of BioCryst, initiated an investigation and notified the FDA. FDA's subsequent investigation revealed that you inflated the effectiveness of BCX-34 in the treatment of psoriasis and T-cell lymphoma and caused BioCryst to submit false and fraudulent statements in the statistical analysis submitted as part of the IND annual report.

As part of a scheme to profit from an increase in the price of BioCryst stock, you falsified reports on the effectiveness of BCX-34 in treating psoriasis and T-cell lymphoma. You caused this information to be deposited with a private and commercial interstate carrier, DHL World Wide Express, for delivery to the FDA.

You conspired with your wife, Renee Peugeot, a clinical study coordinator and subinvestigator directly involved in the clinical studies for BCX-34, to manipulate the results of the clinical studies and commit the offenses listed above. As part of the conspiracy, you generated versions of the drug study randomization schedules to falsely show that lesions that the records showed as improved had been treated with the BCX-34 drug. In fact, the lesions had been treated with the placebo.

FDA's Finding

Section 306(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(a)(2)(A)) requires mandatory debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Your felony conviction under Federal law for making false statements and representations to FDA, committing mail fraud, and conspiring to commit offenses against the United States concerning BCX-34, a new drug under development by BioCryst, constitutes conduct related to the development or approval, including the process for development or approval, of a drug product. Your illegal acts leading to this conviction are a direct violation of the primary legislation regulating drugs.

Under section 306(l)(2) of the Act (21 U.S.C. 335a(1)(2)), mandatory debarment applies when an individual was convicted up to 5 years prior to this notice. Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(A) of the Act permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity for a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing, and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning your debarment. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue the debarment order as proposed in this letter.

A request for hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in your request for hearing that there is no genuine and substantial issue of fact which precludes the order of debarment, the Commissioner of Food and Drugs will enter summary judgment against you, making findings and conclusions, and denying a hearing.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates your debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 01N-0565 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You must file four copies of all submissions under this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Harry W. Snyder, Jr.
Docket No. 01N-0565

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research